K072053

Medical Flow Systems Ltd.

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510(k) Summary:

SmartBlock™ Pain Pump

NOV 0 6 2007

Company Name:
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Trendlines America
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Date prepared: July 20, 2007

Trade Name:
SmartBlock™ Pain Pump

Classification name: Pump, infusion

Common/usual name: Disposable Pain Management System

Product Code: MEB

Regulation No.: 880.5725

Class: II
Panel identification: General Hospital Panel

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Predicate Device:
On-Q Pump, I-Flow Corp. 20202 Widrow Dr., Lake Forest, CA 92630, cleared under 510(k) no. **K063530**.

Description of the device:
The SmartBlock™ Pain Pump is intended to provide continuous and/or intermittent delivery of medication to/or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.

The SmartBlock™ device comprises of the following components:
- Compression unit including solution reservoir (up to 500 ml)
- SmartInfuser regulating set (several versions of flow rate ranges, with or without MultiBolus™)
- 50/60 cc disposable syringe
- Wound dressing
- Medication labes
- Pump lables
- Carry pouch
- FlowSpliter™ (optional)

The SmartBlock™ Pain Pump is designed for the following flow rate options:

	Reference #	Flow Rate Range	Bolus Feature
1	P49520	1-6 ml/hr	Included
2	P49524	5-15 ml/hr	Included
3	P49530	1-6 ml/hr	Not included
4	P49534	5-15 ml/hr	Not included

Indications for Use:
The SmartBlock™ Pain Pump is intended to provide continuous and/or intermittent delivery of medication to/or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.

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Substantial Equivalence:
The SmartInfuser PainPump™ has the same intended use as the **On-Q Pump**, cleared under 510(k) no. **K063530**and has equivalent performance characteristics. It is therefore substantially equivalent to that device.

Conclusion -
The evaluation of the SmartBlock™ Pain Pump does not raise any additional concerns regarding safety and effectivity and may therefore be considered substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 6 2007

Medical Flow Systems, Limited
C/O Mr. Mark Dollinger
President
Treadlines America
2940 West 123rd Terrace
Leawood, Kansas 66200

Re: K072053
Trade/Device Name: SmartBlock™ Pain Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MEB
Dated: September 23, 2007
Received: September 25, 2007

Dear Mr. Dollinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Neil R. P. Ogden

Chiu Lin, Ph.D. for
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K072053

Device Name: SmartBlock™ Pain Pump

Indications for Use: The SmartBlock™ Pain Pump is intended to provide continuous and/or intermittent delivery of medication to/or around surgical wound sites and/or close proximity to nerves for preoperative, perioperative and postoperative regional anesthesia and pain management. Routes of administration may be intraoperative, perineural, percutaneous and epidural.

Prescription Use ___X___ OR Over the Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K072053